PROCESS SPECIFICATION

Active Amendments: None

1. SCOPE.

1.1 Scope. This specification establishes classes of controlled environment for clean rooms and clean work stations and for controlled and noncritical areas. For each class, limits of airborne particulate matter, temperature and humidity are specified.

1.2 Effectivity. This specification is a complete revision of TPS 7-200, dated 5 November 1984, and is effective upon release of the Document Release Notice (DRN). Amendment I, dated 25 March 1988, has been incorporated into this issue. Changed paragraphs from the previous revision are marked by a solid black bar in the left-hand margin.

1.3 Classification.

1.3.1 Clean Rooms and Clean Work Stations. The following classes of controlled environment correspond to identically numbered classes in FED-STD-209. The number used for identification of each class corresponds to the maximum number of particles, .5 micrometers or larger, permitted in one cubic foot of air for that class. Classes are further defined in 3.4.

a. Class 100
b. Class 10,000
c. Class 100,000

1.3.2 Controlled Areas. The following classes of controlled environment do not fall within the definition of "clean room" according to FED-STD-209, and have been designated as "Controlled Areas". The number used for identification of each class corresponds to the maximum number of particles, .5 micrometers or larger, permitted in one cubic foot of air of that class. These classes are further defined in 3.4.

a. Class 200,000
b. Class 300,000
c. Class 400,000
d. Class 1,500,000

1.3.3 Noncritical Areas. Noncritical areas do not fall within the definitions of 1.3.1 or 1.3.2 and are given a special designation (see below). This area is defined as one maintained in accordance with good housekeeping practices.

a. Class GH

2. APPLICABLE DOCUMENTS.

2.1 Government documents. The following documents form a part of this specification to the extent specified herein. Unless otherwise specified, the current issue shall apply.

SPECIFICATIONS

Federal

FED-STD-209	Clean Room and Work Station Requirements, Controlled Environment

2.2 Non-Government documents. The following documents form a part of this specification to the extent specified herein. Unless otherwise indicated, the current issue shall apply.

STANDARDS

American Society for Testing and Materials

ASTM F25	Method for Sizing and Counting Airborne Particulate Contamination in Clean Rooms and Other Dust-Controlled Areas Designed for Electronic and Similar Applications.
ASTM F50	Method for Continuous Sizing and Counting of Airborne Particles in Dust-Controlled Areas Using Instruments Based Upon Light-Scattering Principles.

3. REQUIREMENTS.

3.1 Facilities. Facilities shall be so constructed that the requirements of this specification can be met. See FED-STD-209 for design guidelines.

3.2 Materials.

a. Millipore filter, type HA, black gridded, Millipore Filter Corporation, CAGE 08071, or equivalent.

b. Plastic Petri dish, Millipore Filter Corporation, CAGE 08071, or equivalent.

c. Bottle, 16 oz. Squat-form with wide-mouth screw cap, (Cat. #16195, VWR Scientific, Inc., CAGE 86917, or equivalent).

d. Wipes, prepaint and clean room quality.

3.3 Personnel.

a. All personnel, including supervision and maintenance personnel, working in clean rooms or at clean work stations of Class 100, Class 10,000 or Class 100,000 shall be informed of clean-room procedures by Quality.

b. All personnel, including supervision and maintenance personnel, working in controlled areas covered by this specification, shall receive appropriate training in contamination control area procedures.

c. Authorized observers entering clean rooms (Class 100,000 or better) shall be familiarized with pertinent procedures and shall be accompanied by a certified person.

3.4 Atmospheric Conditions.

3.4.1 Airborne Particulate Matter. Airborne particulate matter shall be monitored in accordance with and shall be within the limits specified by Table I for the partiticle size and monitoring method selected.

3.4.2 Temperature and Humidity. Unless otherwise specified, temperature and humidity of clean rooms and controlled areas shall meet the requirements of Table II. Any method and equipment may be used for monitoring which is capable of assuring control and meets the requirements of Section 4.2.

3.4.3 Airborne Hydrocarbon Control. In Classes 1,500,000 or better, airborne hydrocarbons in ambient air shall be controlled by enforcing the following rules:

1. Operation of internal combustion engines within the area is prohibited.

2. Motors, equipment and operations which distribute, in anyway, (spray, throw, etc.) visible droplets of oil, grease or other lubricants onto the hardware or surfaces which contact the hardware, are prohibited. Visible lubricants on bearings, shafts and other moving parts are acceptable, except where liquid oxygen sensitivity is a factor.

3. Smoking is prohibited.

TABLE I
AIRBORNE PARTICULATE MATTER LIMITS

PARTICLE SIZE EQUAL TO OR GREATER THAN (MICRON)	MONITORING METHOD	MAXIMUM NUMBER OF PARTICLES							
		CLEAN ROOM CLEAN WORK STATION			CONTROLLED AREA				NON-CRITICAL AREA
		CLASS 100	CLASS 10,000	CLASS 100,000	CLASS 200,000	CLASS 300,000	CLASS 400,000	CLASS 1,500,000	CLASS * GH
0.5	automatic (4.6.1.3) (part./cu. ft.)	100	10,000	100,000	200,000	300,000	400,000	1,500,000	N/A
5.0	automatic (4.6.1.3)	N/A	65	650	1500	2000	3000	10,000	N/A
10.0	or volumetric (4.6.1.2) (part./cu. ft.)	N/A	15	150	300	450	600	2,500	N/A
10	Fallout (4.6.1.1) (part./8hr/sq. in.)	N/A	N/A	N/A	650	1000	1400	4,500	N/A
25	Volumetric (4.6.1.2) (part./cu. ft.)	N/A	N/A	20	40	60	80	300	N/A

*** The Class GH working area shall be maintained in accordance with 3.6.3. Monitoring of airborne particulate matter is not applicable to Class GH.**

TABLE II
TEMPERATURE AND HUMIDITY REQUIREMENTS

CLASS / CONDITION	CLASS 100	CLASS 10,000	CLASS 100,000	CLASS 200,000	CLASS 300,000	CLASS 400,000	CLASS 1,500,000	CLASS GH
Temperature	72° F ± 5° F						75° F ± 10° F	80° F ± 20° F
Humidity	35 - 45% R.H.				30 - 65% R.H.		75% R.H. Maximum	No Requirement

3.4.4 **Compressed air.** Compressed air introduced into a controlled environment of Class 1,500,000 or better shall be filtered with adequate control equipment to assure the particulate matter meets the requirements of the area (Table I). The air shall have a dew point of 45°F or less (45 grains of moisture/pound of dry air) upon delivery into the area.

3.5 **Operating Conditions.** Operating regulations shall be established for each Clean Work Station, Clean Room, and Controlled Area, commensurate with the class and type of activity. The regulations shall be established by the using manufacturing organization and approved by the responsible Quality organization. In establishing the regulations, considerations should be given to the following:

a. Restriction of unnecessary traffic.

b. Screened list of personnel approved for access. (Class 100,000 or better).

c. Prohibiting or controlling smoking and eating.

d. Cleanliness of parts entering area.

e. Cleanliness of personnel entering area.

NOTE: Wash room facilities shall be such that personnel entering a controlled area may practice good personal hygiene.

f. Protective clothing requirements.

NOTE: When it has been determined that protective clothing must be worn for the purpose of limiting airborne particulate matter generation by personnel, adequate regulations shall be established concerning laundering and frequency of changing such clothing to ensure that the clothing itself does not contribute to airborne contamination or to the contamination of parts.

g. Prohibiting or controlling contamination generating materials, activities and equipment.

h. Frequency of maintenance.

3.6 **Maintenance.** Any action required to maintain particulate count within parameters established for the particular class designation of an area shall take precedence over any of the scheduled actions defined in 3.6.1 and 3.6.2.

3.6.1 Classes 400,000 or Better.

a. In clean room or clean work stations (classes 100,000 or better), dust and dirt accumulations are prohibited. Cleaning of parts and work surfaces shall be accomplished using wiping material per 3.2. In controlled areas (classes 200,000, 300,000 and 400,000), dust and dirt shall not be allowed to accumulate to visible levels at any work station. Maintenance shall be done on a schedule which will preclude such accumulation. On non-work surfaces, dust and dirt shall be removed frequently and as necessary to maintain airborne particulate counts within specified limits. Eating is prohibited in Class 400,000 or better.

b. Pressure differentials shall be established and maintained as necessary to inhibit flow of air from a less clean into a cleaner area.

c. Filters shall be changed on a schedule based upon their ability to maintain the level of control required for operating efficiency.

3.6.2 Class 1,500,000.

a. At work stations, dust and dirt shall not be allowed to accumulate to visible levels. Maintenance shall be done on a schedule which will preclude such accumulation. Visible dust accumulation on ledges, truss structures, suspended lighting fixtures, etc., shall be removed as necessary to maintain airborne particulate counts within specified limits. Eating shall be controlled as necessary to prevent contamination of hardware.

b. Pressure differentials may be established as required to inhibit flow of contaminated air into the area.

c. Filters shall be changed on a schedule based upon the level of control required.

3.6.3 Glass GH. Accumulations of visible dust and dirt shall be periodically removed on a schedule consistent with production area good house keeping practices.

4. QUALITY ASSURANCE PROVISIONS.

4.1 Responsibility for inspection. Organizationally assigned personnel responsible for performing the requirements described herein are also primarily responsible for ensuring the quality of the process activities. Other personnel within the operating department, or others as deemed appropriate by management may be assigned to verify compliance with requirements listed herein. Quality Assurance departments may perform inspections or audits as necessary to provide adequate oversight of process controls.

4.2 Monitoring procedures for equipment used in process. The process owner or department performing the process shall verify by process audits or inspection that all equipment used in this process are per the requirements specified herein.

4.3 Monitoring procedures for materials used in process. The process owner or department performing the process shall verify by process audits or inspection that all materials used in this process are per the requirements specified herein and are within any applicable shelf life limits.

4.4 Airborne Particulate Matter Sampling Locations.

4.4.1 Non-Laminar-Flow Facilities. The number and location of sampling test points shall be established in accordance with ASTM F25, except that for rooms in excess of 2000 sq. ft., which are only partially used as

work areas, the number and locations of test points may be based on the size of the work area rather than the room size.

4.4.2 Laminar Flow Facilities. Samples shall be taken at work bench height (36 to 40 inches) at points where the air approaches areas of interests.

4.5 Temperature, Humidity and Airborne Particulate Matter Sampling Frequency. Sampling shall be accomplished with a frequency commensurate with the level of control required. The following schedule shall be used until it can be shown that less frequent sampling is satisfactory.

Class	Sampling Frequency
100	Daily
10,000	Daily
100,000	Daily
200,000	Semi-weekly
300,000	Semi-weekly
400,000	Weekly
1,500,000	Semi-monthly

4.6 Test Methods.

4.6.1 Airborne Particulate Matter Monitoring Methods.

4.6.1.1 Fallout. The sizing and counting shall be in accordance with ASTM F25.

a. Location and frequency of sampling shall be in accordance with 4.4 and 4.5 of this specification.

b. Sampling shall be accomplished by placing an uncovered black gridded filter in a Petri dish at the bottom of a squat-form, wide-mouth bottle at each sampling location. Sampling time shall be 8 ± 1 / 2 hours and shall include time of maximum personnel activity in the area.

4.6.1.2 Volumetric. Volumetric monitoring shall be in accordance with ASTM F25, except that location and frequency of sampling shall be in accordance with 4.4 and 4.5 of this specification.

4.6.1.3 Automatic. Automatic monitoring shall be in accordance with ASTM F50, except that location and frequency of sampling shall be in accordance with 4.4 and 4.5 of this specification.

4.7 Rejection Criteria.

a. The airborne particulate requirements of Table I are derived from the Idealized Statistical Average Particle Size Distribution Curves of Figure 1. Because the curves and control points derived therefrom are idealized statistical averages, local and temporary deviations occur, particularly if a facility is operated near the limit of contamination allowed. When an out-of-tolerance determination is made, repeat samples shall be taken as soon as possible, to confirm the out-of-tolerance condition or a return to in-tolerance condition.

b. If an area is confirmed by repeat sampling to be out-of-tolerance, production shall be stopped in the area immediately. Appropriate corrective action shall be taken to return the area to an in-tolerance condition.

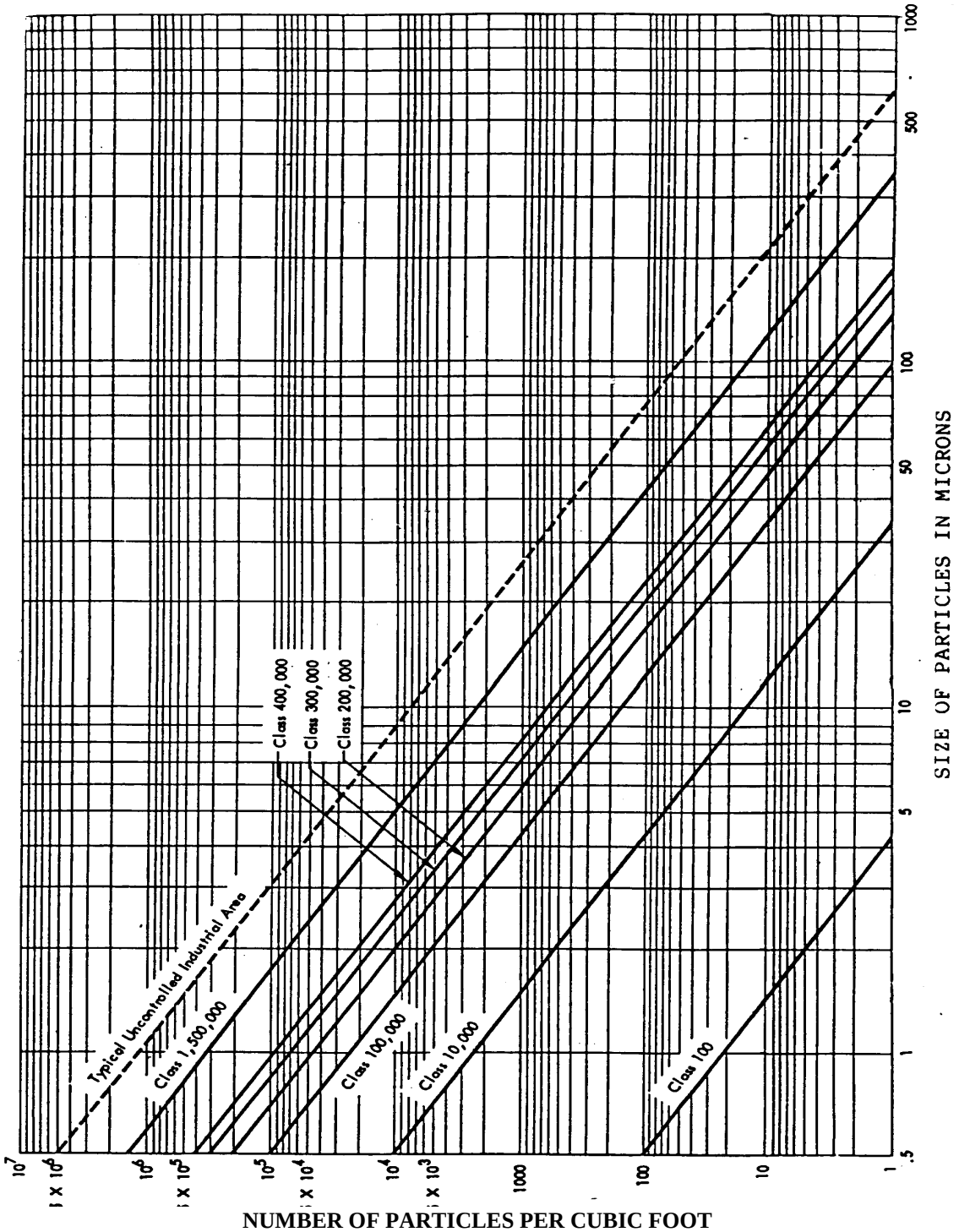

FIGURE 1
IDEALIZED STATISTICAL AVERAGE PARTICLE SIZE DISTRIBUTION CURVES

5. PREPARATION FOR DELIVERY.

This section is not applicable to this specification.

6. NOTES.

6.1 Intended use. This specification is intended to classify controlled environments. Unless otherwise specified by Engineering drawings or specifications, the requirements for temperature, humidity and airborne particulate matter for a particular class shall be per this specification.

6.2 Definitions.

a. Clean Room. An enclosed area employing control over the particulate matter in air with temperature, humidity, and pressure control, as required.

b. Clean Work Station. A work bench or similar working enclosure characterized by having its own filtered air or gas supply.

c. Particle Size. Particle size is expressed as the apparent maximum linear dimension or diameter of the particle.

d. Micron (Micrometer). A unit of measurement equal to one-millionth of a meter or approximately 0.00004 inch. (e.g., 25 microns are approximately 0.001 inch.)

e. Controlled Area. An air conditioned work space or room in which the particle concentration is lower than normal air conditioned spaces. A controlled area is not to be classified as a clean room but some special filtration is required.